IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Christopher Hughes and Judy Hughes	:	
Plaintiffs,	:	
v.	:	
	:	Case No. 14-cv-1476
AbbVie Inc., and Abbott Laboratories Inc.,	:	
Defendants.	:	Jury Trial Demanded

COMPLAINT

Plaintiffs, Christopher Hughes and Judy Hughes, individuals, complaining against Defendants, AbbVie Inc. and Abbott Laboratories Inc., state as follows:

I. PROCEDURAL AND FACTUAL BACKGROUND

A. INTRODUCTION

1. This case involves the prescription drug AndroGel, which is manufactured, sold, distributed and promoted by the Defendants AbbVie Inc. and Abbott Laboratories Inc. (hereinafter jointly "Defendants" or "AbbVie") as a testosterone replacement therapy.

2. Defendants misrepresented that AndroGel is a safe and effective treatment for hypogonadism and a condition they referred to as "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thrombolytic events.

3. AndroGel causes the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thrombolytic events.

4. Defendants failed to adequately warn physicians about the risks associated with the AndroGel and the monitoring required to ensure their patients' safety.

5. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for AndroGel. Further, Defendants engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T" or "low testosterone."

6. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." *Available at*: http://www.isitlowt.com/do-you-have-low-t/low-t-quiz. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

7. As a result of this "disease mongering," as termed by Dr. Adriane Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" have increased exponentially. This has directly related to AndroGel's sales increasing to over $1.37 billion per year.

8. However, consumers of AndroGel were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

B. PARTIES

9. Plaintiffs Christopher Hughes and Judy Hughes are and were at all times relevant hereto United States citizens and citizens of the State of Minnesota, domiciled in Menahga, Wadena County, Minnesota.

10. Defendant AbbVie is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

11. Defendant Abbott Laboratories Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbott Park Road, North Chicago, Lake County, Illinois 60064.

12. By way of background, Unimed Pharmaceuticals Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division which included AndroGel. Then in 2013, Abbott created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

C. JURISDICTION AND VENUE

13. Subject matter of this action arises under 28 U.S.C. § 1332. The parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

14. This Court has personal jurisdiction of the Defendants because the Defendants have their primary place of business in Illinois.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because, inter alia, a substantial part of the events or omissions giving rise to the Plaintiff's claims occurred in, and because the Defendants transact business in, this district.

D. FACTUAL BACKGROUND

1. General Allegations

16. This action is for damages brought on behalf of the Plaintiff Christopher Hughes who was prescribed and supplied with, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

17. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

18. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use and application by men, including, but not limited to, Plaintiff Christopher Hughes.

19. At all times herein mentioned, Defendants were authorized to do business within the states of Minnesota and Illinois.

20. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and

dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

21. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug AndroGel is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

2. Overview

22. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone.

23. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men."

24. In 2000, when the FDA approved AndroGel, the company announced that the market was "four to five million American men." By 2003, the number increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001 -

2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

25. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

26. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

27. Defendants' national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?", "Are you falling asleep after dinner?", "Are you sad and/or grumpy?", and "Do you have a lack of energy?"

28. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morely drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morely admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. TIMES.

29. Since the FDA approved AndroGel, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

30. While running its disease awareness campaign, Defendants promote their product AndroGel as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

31. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

32. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes, heart attacks, pulmonary embolisms and blood clots.

33. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

34. Defendants' advertising paid off in a return of $1.4 billion in sales during the past year, making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg BusinessWeek, *available at:* http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra.

35. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance low T. *See* Singer, *Selling That New-Man Feeling*, *supra*; See *also*, Larry Dobrow, *All-star large pharma marketing team of the year: Androgel*. Jan. 2, 2013, Medical Marketing & Media, *available at:* http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/.

36. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the

use of AndroGel is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

37. There have been a number of studies associating testosterone use in men with an increased risk of heart attacks and strokes.

38. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

39. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

40. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

3. Factual Allegations Common to All Causes of Action

41. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for the treatment of adult males who have low or no testosterone (AndroGel 1.62% was approved in April, 2011). After FDA approval, AndroGel was widely advertised and marketed by Defendant as a safe and effective testosterone replacement therapy.

42. AndroGel, is a hydroalcoholic gel containing testosterone in either 1% or 1.62%, applied to the chest, arms or stomach and enters the body through transdermal absorption. The

AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement.

43. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

44. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

45. In men, testosterone levels normally begin a gradual decline after the age of thirty.

46. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels the next.

47. AndroGel may produce undesirable side effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, pulmonary embolism and death.

48. In some patient populations, AndroGel use may increase the incidence of adverse events and death by over 500%.

49. In addition to the above, AndroGel has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

50. Secondary exposure to AndroGel can cause side effects in others. In 2009 the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes

in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with AndroGel.

51. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

52. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

53. AbbVie's advertising program, sought to create the image and belief by consumers and their physicians that the use of AndroGel was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

54. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroGel. Defendants deceived potential AndroGel users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

55. Defendants concealed material relevant information from potential AndroGel users and minimized user and prescriber concern regarding the safety of AndroGel.

56. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represents that AbbVie adequately tested AndroGel for all likely side effects. The Defendants also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit levels.

57. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff had known the risks and dangers associated with AndroGel, the Plaintiff would not have taken AndroGel and consequently would not have been subject to its serious side effects.

4. Case Specific Facts

58. Plaintiff Christopher Hughes was approximately 57 years old when he was prescribed and used AndroGel for symptoms he attributed to low testosterone as a result of Defendants' advertisements.

59. After taking multiple doses of AndroGel, in or around 2008, Plaintiff Christopher Hughes suffered multiple blood clots in his lungs.

60. On or about November 26, 2013, Plaintiff Christopher Hughes saw a television commercial about testosterone causing pulmonary embolisms, heart attacks and strokes.

61. Prior to November 26, 2013, Plaintiff Christopher Hughes was unaware of any connection between his use of AndroGel and his pulmonary embolisms.

62. The AndroGel Plaintiff Christopher Hughes consumed caused physical and emotional impairment which affected his personal and professional life. As a result of the pulmonary embolisms, Plaintiff Christopher Hughes was hospitalized and prescribed blood thinners.

63. Prior to using AndroGel, Plaintiff Christopher Hughes had no history of significant cardiovascular problems.

64. Plaintiff incurred significant medical expenses as a result of the treatment he underwent to treat his pulmonary embolisms, will incur future medical expenses as his injury is permanent, his ability to labor and earn money has been impaired, he is at increased risk for future health problems and disability, and he suffered physical pain and mental anguish.

65. Had Plaintiff Christopher Hughes known the true risks associated with the use of testosterone medications, including AndroGel, he would not have consumed the AndroGel, and would not have incurred the injuries or damages he did as a result of his use of AndroGel.

II. CAUSES OF ACTION

Count One – Strict Products Liability – Failure to Warn

66. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

67. The Defendants are liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

68. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

69. Defendants failed to adequately warn consumers and/or their health care providers that AndroGel could cause increased hematocrit levels that could cause heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

70. Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking AndroGel it was necessary to frequently monitor hematocrit levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

71. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of AndroGel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

72. As a direct and proximate result of Plaintiff's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

Count Two – Negligence

73. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

74. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of AndroGel.

75. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled,

inspected, distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and failed to adequately test and warn of the risks and dangers of AndroGel.

76. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonable, dangerous side effects, Defendants continued to market AndroGel to consumers including Plaintiff, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that AndroGel marketing materials claim are caused by "Low T".

77. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

78. Defendants' negligence was a proximate cause of the Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

Count Three – Breach of Implied Warranty

79. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

80. Prior to the time that the aforementioned products were used by the Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.

81. Plaintiff was and is unskilled in the research, design and manufacture of medical drugs, including AndroGel, and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using AndroGel.

82. AndroGel was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that AndroGel has dangerous propensities when used as intended and will cause severe injuries to users.

83. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Four - Breach of Express Warranty

84. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

85. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that AndroGel is safe, effective, fit and proper for its intended use. Plaintiff purchased AndroGel relying upon these warranties.

86. In utilizing AndroGel, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that AndroGel is unsafe and unfit for its intended uses.

87. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Five - Fraud

88. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

89. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

90. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroGel. Defendants knew of the foregoing, that AndroGel is not safe, fit and effective for human consumption, that using AndroGel is hazardous to health, and that AndroGel has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

91. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe AndroGel, and Plaintiff would not have used AndroGel, if they were aware of the true facts concerning its dangers.

92. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

Count Six – Negligent Misrepresentation

93. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

94. From the time AndroGel was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that AndroGel was safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

95. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

96. The representations by the Defendants were in fact false, in that AndroGel is not safe, fit and effective for human consumption, using AndroGel is hazardous to health, and AndroGel has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

97. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of AndroGel.

98. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use AndroGel. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used AndroGel. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

99. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

Count Seven – Loss of Consortium

100. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

101. At all relevant times stated herein, the Plaintiff Judy Hughes, was and is the wife and spouse of Plaintiff Christopher Hughes.

102. As a result of the injuries sustained by Plaintiff Christopher Hughes, as set forth above, Plaintiff Judy Hughes has suffered loss of consortium, including but not limited to, mental anguish and the loss of her husband's support, services, society, companionship, comfort, affection, love, and solace.

103. As a result of the injuries sustained by Plaintiff Christopher Hughes, as set forth above, Plaintiffs Christopher Hughes and Judy Hughes sustained damage to their marital relationship.

Punitive Damages Allegations

104. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if fully copied and set forth at length herein.

105. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other AndroGel users and for the primary purpose of increasing Defendants' profits from the sale and distribution of AndroGel. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

106. Prior to the manufacturing, sale, and distribution of AndroGel, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel.

107. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in AndroGel and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in AndroGel. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and

distribution and marketing of AndroGel knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

108. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER

WHEREFORE, Plaintiffs pray for judgment against the Defendants, as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

February 28, 2014

Respectfully Submitted,

Christopher Hughes and Judy Hughes

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